USAID/GEO
GUYANA ECONOMIC OPPORTUNITIES

THE BIOTERRORISM LEGISLATION AND FOOD EXPORTS TO THE U.S.

NEW REGULATIONS FOR REGISTRATION AND NOTIFICATION

A GUIDE FOR EXPORTERS

Prepared by

The New Guyana Marketing Corporation
and
The USAID/GEO Project

Submitted by:
Chemonics International, Inc.
In association with:
Management Systems International, Inc.

To:
United States Agency for International Development
Georgetown, Guyana

Under Contract No. 504-C-00-99-00009-00

November 2003

GEO Technical Report No. 68

Table of Contents

I. INTRODUCTION: What is it the new legislation? What does it mean?

Last year the U.S. enacted new legislation aimed at increasing the safety and security of America's food supply. The new law, entitled, *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act),* was enacted in part as the result of September 11th and the recent increased threat of terrorism. There are two new regulations issued by the Food and Drug Administration (FDA) as part of this new legislation that will directly impact on Guyanese exporters of food products to the U.S. The first targets mainly foreign exporters and the second targets the exporter's agent or importer in the U.S. Both are extremely important and compliance with both is necessary for food products to be allowed into the U.S.

The first regulation requires that foreign[1] food facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. to register with the FDA by December 12, 2003. The second regulation requires advance notification by food importers of human and animal food shipments imported or offered for import. This second regulation also takes effect for imports arriving on or after December 12, 2003.

It should be noted that at the time of the writing of this pamphlet, the new regulations are "interim final rules" which means that the regulations could be modified. It is important that exporters be vigilant for possible modifications. The information for this pamphlet was taken from the FDA website: http://www.cfsan.fda.gov

This factsheet or pamphlet is intended to assist companies who export food products to the U.S. to understand the process and requirements and to provide guidance in registering his or her firm. For those having any questions about the process or for those needing assistance in registering, please feel free to contact:

New Guyana Marketing Corporation
87 Robb Street
Georgetown
Tel. 227-1630
Fax 227-4114
Email: newgmc@networksgy.com

Or

USAID GEO Project
12 Earl's Avenue
Subryanville
Georgetown
Tel. 223-7144
Fax 223-7143
Email: geo@chemonics.net

[1] Note that this regulation also pertains to U.S. food facilities.

II. REGISTRATION OF FOOD FACILITIES

The Bioterrorism Act directs the Government to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To carry out the provisions of the Bioterrorism Act, FDA published *Registration of Food Facilities.* This regulation requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Under this regulation, all affected facilities must register by ***December 12, 2003***. In the event of a potential or actual bioterrorism incident or an outbreak of food-borne illness, facility registration information will help FDA to determine the location and source of the event and permit the agency to quickly notify facilities that may be affected.

This new regulation pertains *only* to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the U.S.

Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

a. Answers to Frequently Asked Questions about Registration

Who must register? The owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them, must register that facility with FDA by **December 12, 2003**. For purposes of registration, a foreign facility must designate a **U.S. agent** (for example a facility's importer or broker), who must live or maintain a place of business in the U.S. and be physically present in the U.S., for purposes of registration.

The following foreign facilities do not need to register:

- Transport vehicles that hold food only in the usual course of their business as carriers.
- Farms.
- Fishing vessels that harvest and transport fish.

However, transporters, farms and fishing vessels that also conduct further downstream processing and exporting must register.

Do all foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S have to register? No. If a foreign facility that manufactures/ processes, packs, or holds food sends it to another *foreign* facility for further manufacturing/processing or packaging before the food is exported to the U.S., only the *second* foreign facility is required to register. **However**, if the second foreign facility performs only a *minor* activity, such as putting on a label, *both* facilities would be required to register. Also, any foreign facility that *packs or holds* food after the last foreign manufacturer/processor of the food must register.

How often must you register? Registration is required only once for each food facility. However, required registration information must be updated if it changes.

What does the registration number mean? Upon registration each food facility will receive a registration number. The number means that the owner of the facility has complied with this rule by registering with FDA. Assignment of the number does not convey FDA approval or endorsement of the facility or its products.

Is there a fee for registration? There is no fee for registration or for updates of registration.

How can a facility register? Registrants must use Form 3537 (see p. 9 of this pamphlet) to register or update a registration. There are two ways to register: over the internet or by international mail.

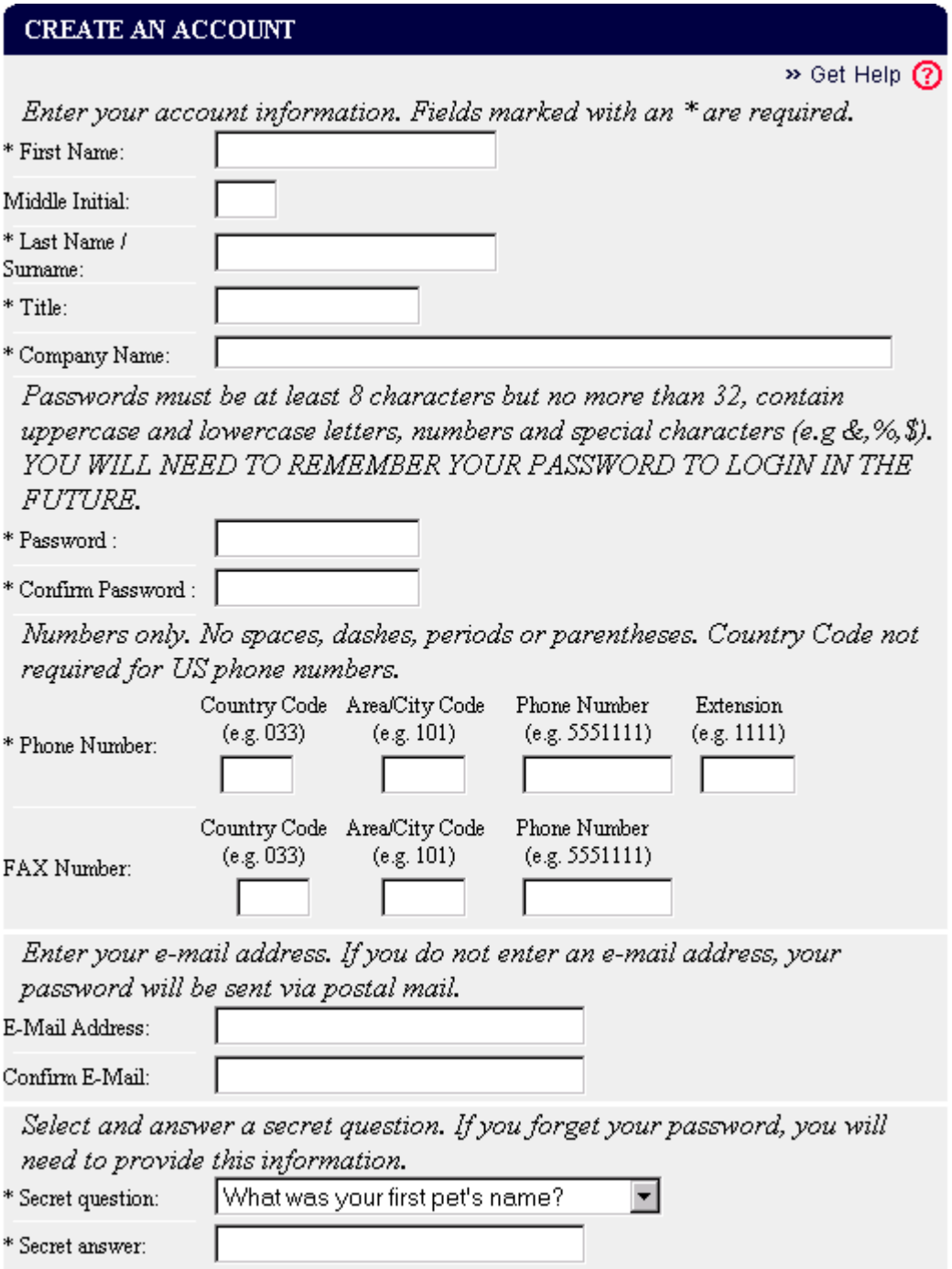
Internet Registration:
FDA encourages registration via the internet as the least costly and most efficient means for the facility as well as FDA. With electronic registration, all required information must be entered before the system will accept the submission. At that point, registrants will receive immediate confirmation of registration and a registration number.

Facilities may register online via the Internet at http://www.cfsan.fda.gov/~furls/ovffreg.html , which will operate 24 hours a day, seven days a week, beginning October 16, 2003. This web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. Registrants can access on line help at www.fda.gov/furls . There is also an Online Registration Help Desk:

- If calling from within the U.S call 1-800-216-7331 or 301-575-0156
- When calling from outside the U.S., call 301-575-0156
- Fax questions to 301-210-0247
- Email questions to furls@fda.gov

Beginning October 16, 2003, these phone numbers will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

Creating an Account:
When logging on the FDA website (http://www.cfsan.fda.gov/~furls/ovffreg.html) to register, the person registering will first be required to create an account number for the firm or facility. Below and on the next page is the form to be filled out in order to create the account.



CREATE AN ACCOUNT

» Get Help

*Enter your account information. Fields marked with an * are required.*

* First Name:

Middle Initial:

* Last Name / Surname:

* Title:

* Company Name:

Passwords must be at least 8 characters but no more than 32, contain uppercase and lowercase letters, numbers and special characters (e.g &,%,$). YOU WILL NEED TO REMEMBER YOUR PASSWORD TO LOGIN IN THE FUTURE.

* Password :

* Confirm Password :

Numbers only. No spaces, dashes, periods or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g. 033)	Area/City Code (e.g. 101)	Phone Number (e.g. 5551111)	Extension (e.g. 1111)
* Phone Number:				
FAX Number:				

Enter your e-mail address. If you do not enter an e-mail address, your password will be sent via postal mail.

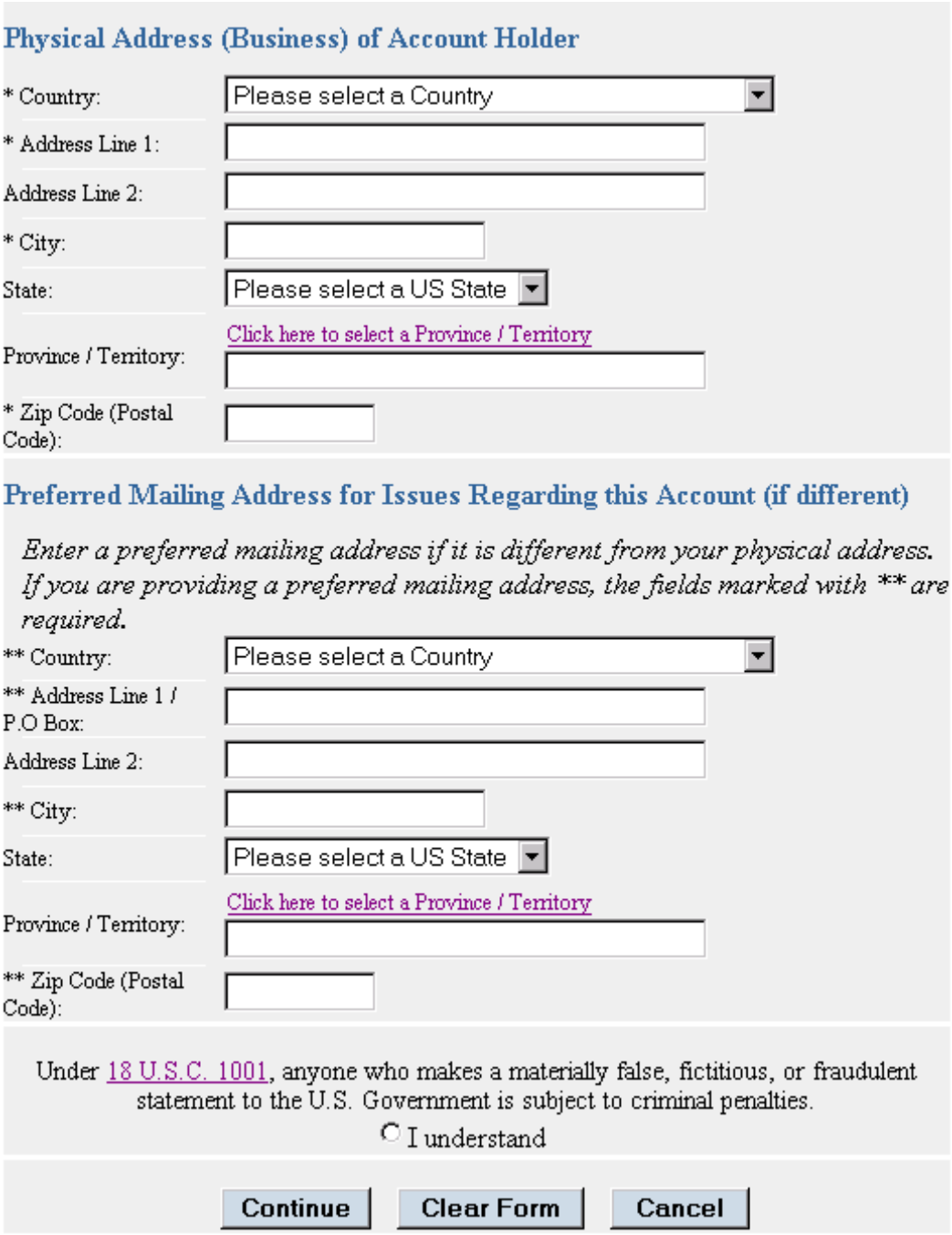
E-Mail Address:

Confirm E-Mail:

Select and answer a secret question. If you forget your password, you will need to provide this information.

* Secret question: What was your first pet's name?

* Secret answer:



Once you have created an account, you can use your password to log into the registration process. The process for registering via the internet is an interactive process. The person doing the registering will be asked to answer a series of questions. The questions and information requested are the same as those on the printed copy – see Section II b and c, beginning on page 9 of this pamphlet for a copy of the printed form and the instructions on how to answer the questions.

Registration by International Mail:

If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from the FDA by calling 1-877-FDA-3882 (1-877-332-3882) or by mailing a request to:

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville MD 20857 USA

The completed form should be mailed to the above address or faxed to (301) 210-0247. Also, as noted immediately below, registrations for multiple facilities may be submitted to the FDA on a CD-ROM.

Is there a mechanism for registering multiple food facilities at one time? FDA will accept multiple registrations submitted in CD-ROM format ISO 9660 (CD-R or CD-RW) data format. These files must be submitted on a Portable Document Format (PDF) of Form 3537 and be accompanied by one signed copy of the certification statement that appears on the registration form. Each submission on the CD-ROM must use the same preferred mailing address in the appropriate block on Form 3537. There is no maximum number of registrations that may be submitted in this manner. However, each registration on a CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company. If the information does not conform to these specifications, FDA will not process the registration(s) and will return the CD-ROM for correction.

FDA will process CD-ROM submissions along with mailed and faxed submissions in the order received.

What information is required? Each registration must include:

- the name, address, and phone number for the facility and its parent company (if applicable);
- the name, address, and phone number of the owner, operator, or agent in charge;
- all trade names the facility uses;
- applicable food product categories;
- a statement certifying that the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration.
- A foreign facility must also provide the name, address, and phone number of its U.S. agent[2]. The foreign facility must also provide the emergency contact phone number for its U.S. agent unless the facility designates another person to serve as the emergency contact.

[2] In response to an inquiry to the Online Registration Help Desk (tel. 301-375-0156) FDA indicated that the "U.S. agent" for purposes of registration could be the broker, the importer, or if the exporter has neither, he/she could use the name of a friend or relative who resides in the U.S. The key requirement for the "U.S. agent" is that the person designated as the agent must be resident in the U.S. and that he or she must have the ability to contact the foreign exporting firm should the need arise.

Is additional information requested? FDA is asking for, but not requiring, certain *optional* information on the registration form. The optional information will help the FDA communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency. For example, some food products are not identified in the list of food categories, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may be the focus of a food-related emergency. Therefore, FDA encourages, but does not require, submission of the information identified as optional on Form 3537.

Is registration information available to the public? No. Neither the list of registered facilities, any registration documents submitted under this regulation, nor any information derived from the list or the documents that would reveal the identity or location of a specific registered person is subject to disclosure.

What if the submitted registration information changes? When a required element of a facility's registration information changes, e.g., change of operator, agent in charge, or U.S. agent, the owner, operator, or agent in charge, or an individual authorized by one of them, must submit an update to the facility's registration within 60 days of the change through the Internet at www.fda.gov/furls or through the paper update process.

What if a facility goes out of business? When a facility goes out of business, its registration must be canceled using Form 3537a, either through the Internet, at www.fda.gov/furls, or through the paper process.

What if a new owner acquires an already-registered facility? The former owner must cancel the facility's registration within 60 days of the change (using Form 3537a), and the new owner must re-register the facility using Form 3537. Both cancellation and re-registration may be completed through the Internet or through the paper process.

What happens if a facility does not register? Failure of a domestic or foreign facility to register, update required elements, or cancel its registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil or a criminal action in Federal court to prosecute persons who attempt to import food products from non-registered firms or facilities. If a foreign facility is required to register but fails to do so, food from that foreign facility that is offered for import into the U.S. is subject to being held at the port of entry in the U.S. If the food must be moved, the private parties involved (i.e., the owner, purchaser, importer, or receiver of the food) must arrange for moving it and promptly notify FDA of its location. The owner, purchaser, importer, or receiver of the food is responsible for any costs associated with moving or storage of the food.

For further information: For more details and information on the specific requirements for facility registration, please refer to the interim final rule itself. The interim final rule is available at http://www.cfsan.fda.gov/

Form 3537

Food Facility Registration Form

Form 3537 on the following pages was downloaded from the FDA website. The printed form is intended for those who wish to register by mail. Those planning to register via the internet, can use the printed form as a guide to determine the information required or the questions they will be asked during the registration process.

The FDS website offers additional assistance in navigating the registration process. Below are several of the webpages that offer assistance:

http://www.cfsan.fda.gov/~furls/ovffreg.html - website for creating an account and registering your facility.

http://www.cfsan.fda.gov/~furls/helpf.html lists on-line help for various tasks – creating an account, registering, etc.

http://www.cfsan.fda.gov/~furlst/tut-toc.html has step by step tutorials for creating an account, logging in, registration, etc.

http://www.cfsan.fda.gov/~furls/ffrmqa.html#requirement provides answers to frequently asked questions

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2006
See OMB Statement at end of form

FDA USE ONLY

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

USE BLUE OR BLACK INK ONLY

Date: _____ **(MM/DD/YYYY)**

Section 1 - TYPE OF REGISTRATION

1a. ○ **DOMESTIC REGISTRATION**	○ **FOREIGN REGISTRATION**
1b. ○ **INITIAL REGISTRATION**	○ **UPDATE OF REGISTRATION INFORMATION**

If update, provide the following:
Facility Registration Number: _____ **PIN** _____

Check all that apply and further identify changes in the applicable sections.	☐ United States Agent Change – Foreign facilities only
☐ Facility Name Change	☐ Seasonal Facility Dates of Operation Change
☐ Facility Address Change (see instructions)	☐ Type of Activity Change
☐ Preferred Mailing Address Change	☐ Type of Storage Change
☐ Parent Company Change	☐ Human Food Product Category Change
☐ Emergency Contact Change	☐ Animal Food Product Category Change
☐ Trade Name Change	☐ Operator or Agent in Charge Change

1c. ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY? Yes ○ No ○

If "yes", provide the following information, if known.

Previous owner's name:	Previous owner's registration number:

Section 2 - FACILITY NAME / ADDRESS INFORMATION

FACILITY NAME:	
FACILITY STREET ADDRESS, Line 1:	
FACILITY STREET ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):
FAX NUMBER (OPTIONAL; Include Area/ Country Code):	E-MAIL ADDRESS (OPTIONAL):

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2006
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 3 - PREFERRED MAILING ADDRESS INFORMATION complete this section only if different from Section 2, Facility Name/Address Information (OPTIONAL)	
NAME:	
ADDRESS, Line 1:	
ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/ Country Code):
FAX NUMBER (Include Area/ Country Code):	E-MAIL ADDRESS:

Section 4 - PARENT COMPANY NAME / ADDRESS INFORMATION (IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 AND 3). IF INFORMATION IS THE SAME AS ANOTHER SECTION, CHECK WHICH SECTION: SECTION 2 ◯ or SECTION 3 ◯	
NAME OF PARENT COMPANY:	
STREET ADDRESS OF PARENT COMPANY, Line 1:	
STREET ADDRESS OF PARENT COMPANY, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/ Country Code):
FAX NUMBER (OPTIONAL; Include Area/Country Code):	E-MAIL ADDRESS (OPTIONAL):

Section 5 - FACILITY EMERGENCY CONTACT INFORMATION (**OPTIONAL** FOR FOREIGN FACILITIES; FDA WILL USE YOUR U.S. AGENT AS YOUR EMERGENCY CONTACT UNLESS YOU CHOOSE TO DESIGNATE A DIFFERENT CONTACT HERE.)	
INDIVIDUAL'S NAME (OPTIONAL):	
TITLE (OPTIONAL):	EMERGENCY CONTACT PHONE (Include area/ country code):
E-MAIL ADDRESS (OPTIONAL):	

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2006
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 6 – TRADE NAMES (IF THIS FACILITY USES TRADE NAMES OTHER THAN THAT LISTED IN SECTION 2 ABOVE, LIST THEM BELOW (E.G., "ALSO DOING BUSINESS AS," "FACILITY ALSO KNOWN AS"):
ALTERNATE TRADE NAME #1:
ALTERNATE TRADE NAME #2:
ALTERNATE TRADE NAME #3:
ALTERNATE TRADE NAME #4:

Section 7 - UNITED STATES AGENT (TO BE COMPLETED BY FACILITIES LOCATED OUTSIDE ANY STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.)		
NAME OF U.S. AGENT:		
TITLE (OPTIONAL):		
ADDRESS, Line 1:		
ADDRESS, Line 2:		
CITY:	STATE:	ZIP CODE:
U.S. AGENT PHONE NUMBER (Include Area Code):	EMERGENCY CONTACT PHONE NUMBER (Include Area Code):	
FAX NUMBER (OPTIONAL; Include Area Code):	E-MAIL ADDRESS (OPTIONAL):	

Section 8 - SEASONAL FACILITY DATES OF OPERATION (GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS) **(OPTIONAL)**
DATES OF OPERATION:

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2005
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 9 - TYPE OF ACTIVITY CONDUCTED AT THE FACILITY

(CHECK ALL TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING/PROCESSING, PACKING OR HOLDING OF FOOD) **(OPTIONAL)**

☐ Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	
☐ Acidified / Low Acid Food Processor	☐ Labeler / Relabeler
☐ Interstate Conveyance Caterer/Catering Point	☐ Manufacturer / Processor
☐ Molluscan Shellfish Establishment	☐ Repacker / Packer
☐ Commissary	☐ Salvage Operator (Reconditioner)
☐ Contract Sterilizer	☐ Animal food manufacturer / processor / holder

Section 10 – TYPE OF STORAGE (FOR FACILITIES THAT ARE PRIMARILY HOLDERS) **(OPTIONAL)**

☐ Ambient (neither frozen nor refrigerated) Storage	☐ Refrigerated Storage	☐ Frozen Storage

Section 11a - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION

To be completed by all food facilities. Please see instructions for further examples.
IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.

☐ 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	☐ 7. CHEESE AND CHEESE PRODUCTS [21 CFR 170.3 (n) (5)]
☐ 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)	☐ 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (36), (43)]
☐ 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	☐ 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]
☐ 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (16), (35)]	☐ 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]
☐ 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (36)]	☐ 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]
☐ 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2006
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 11a - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (CONTINUED)

To be completed by all food facilities. Please see instructions for further examples.
IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.

12. DIETARY SUPPLEMENTS
- ☐ Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]
- ☐ Vitamins and Minerals [21 CFR 170.3 (o) (20)]
- ☐ Animal By-Products and Extracts (Optional Selection)
- ☐ Herbals and Botanicals (Optional Selection)

☐ 13. DRESSINGS AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]

☐ 14. FISHERY/SEAFOOD PRODUCTS [21 CFR 170.3 (n) (13), (15), (39), (40)]

☐ 15. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)

☐ 16. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9), (41), 21 CFR 170.3 (o) (21)]

☐ 17. FRUITS AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]

☐ 18. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]

☐ 19. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]

☐ 20. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]

☐ 21. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]

☐ 22. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]

☐ 23. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]

☐ 24. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)]

☐ 25. NUT AND EDIBLE SEED PRODUCTS [21 CFR 170.3 (n) (26), (32)]

☐ 26. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]

☐ 27. SHELL EGG AND EGG PRODUCTS [21 CFR 170.3 (n) (11), (14)]

☐ 28. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]

☐ 29. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (25)]

☐ 30. SOUPS [21 CFR 170.3 (n) (39), (40)]

☐ 31. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]

☐ 32. VEGETABLES AND VEGETABLE PRODUCTS [21 CFR 170.3 (n) (19), (36)]

☐ 33. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]

☐ 34. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]

☐ 35. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS),OR STARCH [21 CFR 170.3 (n) (1), (23)]

☐ 36. MOST/ALL HUMAN FOOD PRODUCT CATEGORIES (Optional Selection)

☐ 37. NONE OF THE ABOVE MANDATORY CATEGORIES

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2005
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 11b - GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION (OPTIONAL)

☐ 1. GRAIN PRODUCTS (E.G., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE AND WHEAT)	☐ 14. MILK PRODUCTS
☐ 2. OILSEED PRODUCTS (E.G., COTTONSEED, SOYBEANS, OTHER OIL SEEDS)	☐ 15. MINERALS
☐ 3. ALFALFA AND LESPEDEZA PRODUCT	☐ 16. MISCELLANEOUS AND SPECIAL PURPOSE PRODUCTS
☐ 4. AMINO ACID	☐ 17. MOLASSES
☐ 5. ANIMAL-DERIVED PRODUCTS	☐ 18. NON-PROTEIN NITROGEN PRODUCTS
☐ 6. BREWER PRODUCTS	☐ 19. PEANUT PRODUCTS
☐ 7. CHEMICAL PRESERVATIVES	☐ 20. RECYCLED ANIMAL WASTE PRODUCTS
☐ 8. CITRUS PRODUCTS	☐ 21. SCREENINGS
☐ 9. DISTILLERY PRODUCTS	☐ 22. VITAMINS
☐ 10. ENZYMES	☐ 23. YEAST PRODUCTS
☐ 11. FATS AND OILS	☐ 24. MIXED FEED (POULTRY, LIVESTOCK, AND EQUINE)
☐ 12. FERMENTATION PRODUCTS	☐ 25. PET FOOD
☐ 13. MARINE PRODUCTS	☐ 26. MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES

Section 12 – OWNER, OPERATOR, OR AGENT IN CHARGE INFORMATION

NAME OF ENTITY OR INDIVIDUAL WHO IS THE OWNER, OPERATOR, OR AGENT IN CHARGE

PROVIDE THE FOLLOWING INFORMATION, IF DIFFERENT FROM ALL OTHER SECTIONS ON THE FORM. IF INFORMATION IS THE SAME AS ANOTHER SECTION OF THE FORM, CHECK WHICH SECTION:

SECTION 2 ○ SECTION 3 ○ SECTION 4 ○ SECTION 7 ○

STREET ADDRESS, Line 1:	
STREET ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):
FAX NUMBER (OPTIONAL; Include Area/ Country Code):	E-MAIL ADDRESS (OPTIONAL):

Form Approval: OMB No. 0910-0502
Expiration Date: 10/31/2006
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 13 - CERTIFICATION STATEMENT	
The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.	
SIGNATURE OF SUBMITTER	
PRINT NAME OF THE SUBMITTER	
CHECK ONE BOX: ◯ A. OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED) ◯ B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION (FILL IN BELOW)	
IF YOU CHECKED BOX B ABOVE, INDICATE WHO AUTHORIZED YOU TO SUBMIT THE REGISTRATION: ◯ OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED) ◯ _____ NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADDRESS BELOW)	
ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL:	
AUTHORIZING INDIVIDUAL STREET ADDRESS, Line 1:	
AUTHORIZING INDIVIDUAL STREET ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):
FAX NUMBER (OPTIONAL; Include Area/ Country Code):	E-MAIL ADDRESS (OPTIONAL):

MAIL COMPLETED FORM TO U.S. FOOD AND DRUG ADMINISTRATION, HFS-681, 5600 FISHERS LANE, ROCKVILLE, MD 20857, OR FAX IT TO (301) 210-0247.

FDA USE ONLY	
DATE REGISTRATION FORM RECEIVED	DATE NOTIFICATION SENT TO FACILITY

Public reporting burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CFSAN/PRB Comments HFS-024
5100 Paint Branch Parkway
College Park, MD 20740-3835

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number

Instructions for Form 3537
Food Facility Registration Form

NOTE: Form 3537 is used to register a food facility or to provide an update to an existing registration. If you wish to cancel a food facility registration, you must use Form 3537a. The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must fill out, sign, and submit this form.

An individual (other than the owner, operator, or agent in charge of the facility) who submits this form to FDA must, in section 13 of the form (certification statement), identify by name the individual who authorized submission of the registration. Form 3537 must be signed and printed or typed with black or dark blue ink. If there is no information available for a specific block in a mandatory section, enter the words "Not Available," "N/A," or "None" in that block unless specified otherwise in these instructions. Do not make any entries or marks in the parts of the form designated "FDA USE ONLY". Some sections of the form contain a circle for making a selection. Check the circle when making a selection. All sections on these forms are mandatory unless described otherwise. Forms that are incomplete or illegible will not be processed and may considerably delay a requested action (such as issuance of a Food Facility Registration Number).

Date: Enter the date in the format MM/DD/YYYY. Example: 10/31/2003

Section 1 – TYPE OF REGISTRATION
Subsection 1a. Check the circle for only one of the two choices. Domestic means that the facility is located in any State or Territory of the U.S., in the District of Columbia, or in the Commonwealth of Puerto Rico. Foreign means all others.

Subsection 1b. – INITIAL REGISTRATION
Check the circle for Initial Registration only if this is the first time you have registered this facility with FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Subsection 1b. – UPDATE OF REGISTRATION INFORMATION
If you are updating information for a Food Facility Registration, please provide the current Registration Number in the space provided. Enter the Personal Identification Number (PIN) that was provided upon receipt of the Food Facility Registration Number in the space marked PIN. A form submitting an update will not be processed without the appropriate Registration Number and PIN.

Subsection 1b. – Update Information
Check the circle for each update that applies. If this is a new registration, leave this section blank.

Subsection 1c. – NEW OWNER INFORMATION
If you are a new owner of a previously registered facility, you must re-register. Please provide the previous owner's name and registration number, if known.

Section 2 – FACILITY NAME/ADDRESS INFORMATION
Provide the requested information in the blocks provided. If the facility and address are already listed with the FDA for some other purpose, be sure to use the exact same facility name and address for Section 2.

Section 3 – PREFERRED MAILING ADDRESS INFORMATION (OPTIONAL)

If you prefer to be contacted at an address other than that of the facility, please print or type the requested information in the blocks provided in this section of the form.

Section 4 – PARENT COMPANY NAME/ADDRESS INFORMATION (IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 AND 3)

Complete this section only if the food facility is owned by a parent company.

Section 5 – FACILITY EMERGENCY CONTACT INFORMATION (OPTIONAL FOR FOREIGN FACILITIES)

Domestic facilities must provide the information requested in this section. You must supply at least one telephone number. Providing an individual's name, title, and e-mail address is optional. For foreign facilities, FDA will assume that your U.S. agent is your emergency contact unless you provide alternative information in this section.

Section 6 – TRADE NAMES

"Trade name" is the name or names under which the facility conducts business, or additional names by which the facility is known. If your food facility uses a trade name other than the one listed in Section 2, please print or type the additional trade name(s) in this section. If your food facility does not have any other trade name, enter the word "None" in the appropriate blocks.

Section 7 – UNITED STATES AGENT

Foreign food facilities must have a U.S. Agent. The U.S. Agent must reside or maintain a place of business in the U.S. and be physically present in the U.S. Please print or type the information requested in this section. The U.S. agent's fax number and e-mail address are optional. A U.S. agent's emergency contact phone number must be provided unless the facility has designated an alternate emergency contact in section 5.

Section 8 – SEASONAL FACILITY DATES OF OPERATION (OPTIONAL)

If your food facility operates only during parts of the year, such as during the harvest season, you may enter the date ranges when the facility operates. Example: "Open June 1st through August 31st and October 1st through December 20th."

Section 9 – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)

You may fill in all of the circles that apply to your facility.

Section 10 – TYPE OF STORAGE (OPTIONAL)

This section applies to facilities that are primarily holders (facilities used for storage). You may check all of the circles that apply. If your facility is strictly a refrigerated, frozen, or ambient (neither frozen nor refrigerated) storage facility, you should check the appropriate circle. If more than one choice applies, you should check all that apply.

Section 11a – GENERAL PRODUCT CATEGORIES – FOOD FOR HUMAN CONSUMPTION

All food facilities must complete this section. Check all of the circles that apply to your facility. If you manufacture/process, pack, or hold food that fits into one or more of these categories, check the circle for each category of food manufactured/processed, packed or held at your facility. If none of these categories applies to your facility, select Item 37 (NONE OF THE ABOVE MANDATORY CATEGORIES). If your facility manufactures/processes, packs, or holds food in most or all of the categories in section 11a, you may select Item 36 "MOST/ALL HUMAN FOOD PRODUCT CATEGORIES" instead of selecting all applicable categories. Additional information and cross references can be found at http://www.fda.gov/search/databases.html#pcb (Product Code Builder).

Section 11b – GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION (OPTIONAL) This section only applies to food for animals. You may check the circle for each category of animal food manufactured/processed, packed or held at your facility. If your facility manufactures/processes, packs, or holds food in most or all of the categories in section 11b, you may select Item 26, "MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES" instead of selecting all applicable categories

Section 12 –OWNER, OPERATOR, OR AGENT IN CHARGE INFORMATION
If the contact information for the owner, operator, or agent in charge is the same as that in another section of the form, check the circle corresponding to that section; otherwise enter the information as requested. The fax number and e-mail address for the owner, operator, or agent in charge are optional.

Section 13 --CERTIFICATION STATEMENT
Either the owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting the form to FDA, or by authorizing an individual to submit the form to FDA, the owner, operator, or agent in charge of the facility is certifying that the information contained in the form is true and accurate. If an individual authorized by the owner, operator, or agent in charge of the facility submits the form to FDA, that individual also certifies that the information contained in the form is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge of the facility must identify in this section the name and contact information for the individual who authorized submission of the registration. Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. government is subject to criminal penalties under 18 U.S.C 1001.

SIGNATURE: The submitter is required to sign this form in black or dark blue ink.

NAME OF PERSON SUBMITTING THE REGISTRATION FORM: Print or type the name of the submitter in this space.

CHECK ONE BOX: If the submitter is the owner, operator, or agent in charge, check circle A, "OWNER, OPERATOR, OR AGENT IN CHARGE." If the submitter is an individual authorized by the owner, operator, or agent in charge (such as an administrative employee), check circle B, "INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION."

If you checked circle B, check either the circle, "Owner, operator, or agent in charge" if the owner, operator, or agent in charge authorized you to submit the registration, or the circle, "_____(name of individual who authorized registration on behalf of the owner, operator, or agent in charge)," if someone other than the owner, operator, or agent in charge authorized you to submit the registration. If you checked, "owner, operator, or agent in charge," you are finished with the form. If you checked, "_____(name of individual who authorized registration on behalf of the owner, operator, or agent in charge), complete the name and address information for the individual who authorized you to submit the registration on behalf of the owner, operator, or agent in charge. The fax number and e-mail address for that individual are optional.

Do not mail these instructions back to the FDA with your form. Keep them with your records.

Mail completed Form 3537 to U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857, or FAX it to (301) 210-0247.

III. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

The Bioterrorism Act requires that the FDA receive prior notice of food imported into the United States, **beginning on December 12, 2003**. This regulation is aimed at U.S. importers, not foreign exporters. However, much of the information that the U.S. importer is required to submit is information that must come from the exporter. We provide here an overview of these notification requirements.

Most of the prior notice information required by the interim final rule is data which is currently provided by importers or brokers to the Bureau of Customs and Border Protection (CBP) when foods arrive in the United States. The Bioterrorism Act now requires that this information also be provided to FDA in advance of an imported food's arrival in the United States. FDA will use this information to review, evaluate, and determine whether to inspect the imported food. Nearly all of the current imported food shipments can comply by using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS). Prior notice can be submitted either through ABI/ACS or FDA's Prior Notice (PN) System Interface beginning December 12, 2003[3]. The Prior Notice (PN) System Interface is not yet operational but is scheduled to be available in December at www.access.fda.gov .

When must prior notice be submitted? Prior notice must be received and confirmed electronically by FDA no more than 5 days before arrival and, as specified by the mode of transportation below, no fewer than:

1. 2 hours before arrival by land by road
2. 4 hours before arrival by air or by land by rail
3. 8 hours before arrival by water
4. FDA has not set any specific time limit for receipt of prior notice for hand carried or accompanied food products. However, note that the food must be accompanied by the FDA confirmation.

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. The parcel must be accompanied by the FDA's confirmation of receipt of prior notice.

How must the prior notice be submitted? Prior notice must be submitted electronically. Prior notice for international mail food shipments, other transaction types that cannot be made through ABI/ACS, or articles of food that have been refused admission under section 801(m)(1) of the Federal Food, Drug, and Cosmetic Act must be submitted to the

[3] The Automated Commercial System (ACS) is the system used by the U.S. Customs Service to track, control, and process all commercial goods imported into the United States. The Automated Broker Interface is an integral part of ACS that permits qualified participants to file import data electronically with Customs. ABI is a voluntary program available to brokers, importers, carriers, port authorities, and independent service centers.

FDA PN System Interface at www.access.fda.gov . Beginning on December 12, 2003, technical assistance in submitting prior notice will be available via telephone and fax at the following numbers:

- For the United States, call 1-800-216-7331 or 301-575-0156
- From all other countries and locations, call 301-575-0156
- Send a fax to 301-210-0247

This technical assistance will be available on business days from 7 AM until 11 PM U.S. Eastern Time. Requests for assistance may also be emailed to furls@fda.gov . For assistance with ABI/ACS transmission, the importer or broker should contact his/her CBP client representative.

Both the CBP and FDA systems for prior notice will be available 24 hours a day, 7 days a week for information submission beginning December 12, 2003.

If the ABI/ACS is not working, then prior notice must be submitted using the FDA PN System Interface. If the FDA PN System Interface does not appear to be working properly, the online Help Desk should be contacted first. If the system is not working, then the required prior notice information must be submitted by fax or email. The fax number(s) and email address(es) where they can be sent will be posted on the FDA website (www.fda.gov).

Who must submit prior notice? Any individual with knowledge of the required information may submit the prior notice, including, but not limited to, brokers, importers, and U.S. agents.

What food is subject to the requirement for submitting prior notice? Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of the interim final rule, "food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles. For purposes of the interim final rule and complying with prior notice of imported food shipments, "food" does not include food contact substances (e.g. packaging materials) or pesticides. Prior notice is required for food that will be used, stored or distributed in the United States. This includes gifts, trade samples and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

What foods are excluded from the prior notice requirement? Foods that are excluded from the prior notice requirement are: (1) food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution); (2) food that is exported without leaving the port of arrival until export; (3) meat food products, poultry products and egg products that are subject to the exclusive jurisdiction

of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act; and (4) food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States.

Will FDA provide confirmation of receipt of prior notice? Yes. FDA will issue a confirmation of prior notice to the transmitter upon successful receipt of the prior notice information.

What information must be included in the prior notice? The prior notice must be submitted electronically and contain the following information:

- Identification of the submitter, including name, telephone and fax numbers, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
- Entry type and CBP identifier
- The identification of the article of food, including complete FDA product code, the common or usual name or market name, the ***estimated*** quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable)
- The identification of the manufacturer
- The identification of the grower, if known
- The FDA Country of Production
- The identification of the shipper, except for food imported by international mail
- The country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
- The anticipated arrival information (location, date, and time) or, if the food is imported by international mail, the U.S. recipient (name and address)
- The identification of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States
- The identification of the carrier and mode of transportation, except for food imported by international mail
- Planned shipment information, except for food imported by international mail

Does the carrier need the prior notice confirmation upon arrival? It is prudent to have the confirmation. For a prior notice that is submitted through the ABI/ACS interface, the prior notice confirmation number together with a "PN received" message will be made available to the filer through the ACS/ABI interface. If prior notice is submitted through the FDA PN System Interface, then the transmitter will receive a confirmation online as soon as the submission is confirmed. To make it easier for the carrier or individual at the port, the carrier should have a copy of the confirmation, which includes a prior notice confirmation number in his/her possession. For international mail packages, the Prior Notice Confirmation Number must accompany the package. For food carried by or

otherwise accompanying an individual arriving in the United States, the Prior Notice Confirmation Number must accompany the food.

Can an incomplete prior notice be corrected? Yes. If the transmission fails the validation, it will be rejected and the transmitter will have an opportunity to make corrections.

The FDA PN System Interface has Help features and interactive feedback to assist the submitter and minimize spelling mistakes and omissions. In addition, the online Help Desk will be available to assist users, beginning December 12, 2003. The Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

Confirmation means the information has been received and the information is complete. Subsequent system and manual review by FDA staff may result in inspection of the imported food upon arrival.

What must be done if information changes after prior notice confirmation has been received? If any of the following required information changes after confirmation, then a new prior notice must be submitted:

- Identification of the submitter, including name, telephone and fax numbers, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
- Entry type and CBP identifier
- The identification of the article of food, except the estimated quantity
- The identification of the manufacturer
- The identification of the grower, if known
- The FDA Country of Production
- The identification of the shipper
- The country from which the article of food is shipped or, for food imported by international mail, the anticipated date of mailing
- The U.S. recipient (name and address) if the food is imported by international mail
- The identification of the importer, owner, and consignee
- The identification of the carrier and mode of transportation
- Planned shipment information unless the food will not be imported

Does food that has been refused for inadequate prior notice require any additional information in the prior notice? Yes. In the event that a food shipment is being held because the prior notice was not received in time, then the shipments prior notice or a revised prior notice must include the port of arrival, the location where the refused food is being held, the date it arrived or will arrive at that location, and the identification of the contact person at that location.

What are the consequences of failing to submit adequate prior notice information of an imported food shipment? Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in secure storage. FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances. FDA also intends to provide guidance to its staff on enforcing the prior notice requirements after a transition period. FDA's guidance documents will be available to the public, and FDA will publish a notice of availability in the *Federal Register*.

For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at http://www.cfsan.fda.gov .